Remarks

This Amendment is in response to the Office Action dated **September 8, 2009.** The Office Action rejected claims 1, 92-94, and 98-101 under 35 USC § 102(e) over Richter (US 6,315,794); rejected claims 1, 91, 95, 100, 101, 108-110, 114, 119-120 under 35 USC § 102(b) over Venbrux (US 5,443,497); rejected claims 1, 91-92, 94, 98-101, and 108 under 35 USC § 102(e) over Kranz (US 6,312,456); rejected claims 1, 91, 92, 94, 96-100, 108-111, 113, and 115-119 under 35 USC § 102(b) over Scott (US 5,383,928); and rejected claims 1, 91-101, and 105-123 under 35 USC § 103 over Berg (US 5,464,650) in view of Scott, Nolting (US 6,488,701) and Jang (US Pub. No. 2004/0106985).

Applicant notes that in the Office Action the Examiner lined out several references in the IDS of July 14, 2009. Applicant further notes that this IDS was signed by the Examiner. The previous IDS of May 15, 2009 was additionally singed by the Examiner. Applicant presumes that all the references cited in the IDSs were considered by the Examiner because the references that were lined out in the IDS of July 14, 2009 were duplicates of those cited in the IDS of May 15, 2009. **Applicant herein requests an initialed IDS showing consideration of each of the submitted and/or cited references** of the IDSs of May 15, 2009 and July 14, 2009.

Claims 1 and 109 are herein amended. To add further clarity, these claims have been amended to recite, "a first biocompatible coating adhered directly on at least the metal outer surface of the first end portion of the main body portion" and "a polymer or a drug coating adhered directly on at least the metal outer surface of the first end portion of the main body portion," respectively. Support for these amendments can be found in the Specification at least in paragraphs [0042] and [0044].

. In light of the foregoing amendments and following comments, Applicant requests reconsideration.

Claim Rejections – Section 102

Rejections over Richter

Claims 1, 92-94, and 98-101 were rejected over Richter. This rejection is *traversed*.

In rejecting the aforementioned claims over Richter, the Office Action asserts that

the "coating 202 [of Richter] comprises a metallic material which is encompassed by the broadly claimed 'drug', and in view of the broad definition afforded the term in the specification at paragraph [0050] of the published application. . . ." Pages 2-3. The Office Action's assertion is erroneous. Richter discloses a "[s]econd coating 202 [which] comprises a suitable radiopaque material such as gold, platinum, silver and tantalum. . . ." Column 4, lines 65-66.

Applicant first notes that paragraph [0050] reads as follows:

> [0050] The coating 18 may also be used as a drug delivery system to prevent restenosis or for other treatment. The drugs may include radiochemicals to irradiate and prohibit tissue growth. Angioplasty and stent deployment may cause injury of the endothelial cell layer of blood vessels, causing smooth muscle cell proliferation, leading to restenosis. To control smooth muscle cell growth endothelialization of cells on the inner wall surface of vessels will prevent or prohibit the smooth muscle growth. To stimulate endothelialization without provoking smooth muscle cell proliferation human growth factors may be included in the outer layer and delivered. Growth factors include VEGF, TGF-beta, IGF, PDGF, FGF, etc. These growth factors are dispersed in the matrix of the outer polymer coating 18 of the stent. All such materials are referred to herein generally as "drugs".

Nowhere in paragraph [0050] is there any disclosure that gold in the form of a radiopaque coating, as disclosed in Richter, constitutes a drug.

A person having ordinary skill in the art would not consider the radiopaque materials of gold, platinum, silver, and tantalum as disclosed in Richter to be a drug, as claimed. Indeed, the Office Action has provided no showing that 'gold' is considered to be a drug and, moreover, no showing that gold, as used in Richter (i.e., as a radiopaque material) can be considered a drug. Even if, for the sake of argument only, the Examiner could establish that gold, in some forms, is used in a drug, that does not mean that when provided in the form of a radiopaque coating as disclosed in Richter, that it functions as a drug.

Finally, Richter does not refer to gold, platinum, silver, and tantalum as drugs.

In sum, Richter does not disclose a drug as is claimed.

Further as to claim 99 which requires a mesh, the Final Office Action has not pointed out where Richter discloses a mesh. As such, a *prima facie* case has not been made as to this claim.

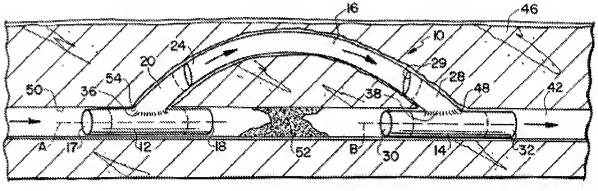
Consequently, Applicant's request withdrawal of the rejection of independent claim 1 and dependent claims 92-94 and 98-101, which depend from claim 1.

Rejections over Venbrux

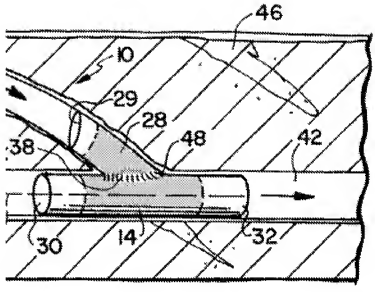
Claims 1, 91, 95, 100, 101, 108-110, 114, and 119-120 were rejected over Venbrux. In rejecting the aforementioned claims over Venbrux, the Office Action asserts, "Venbrux disclose in figure 1 an expandable stent (12 or 14) comprising an end portion having a coating thereon of adhesive or other polymer wherein the middle portion is free of the coating." Page 3. Applicant disagrees.

Venbrux discloses that "portions of the stents and tubular members may be covered with PTFE material or other coating, as indicated by the dashed lines in FIG. 1. The central member can then be sewn or adhered to the covered portions." Column 3, lines 54-57.

FIG. 1



In contrast to the Office Action's assertion, the portions of Venbrux that are covered with PTFE material or other 'coating' do not consist of the ends of the stent. Instead, the 'coated' region(s) of the stents 12, 14 and proximal and distal members 20, 28 are the middle regions thereof, shown below as the 'grayed' out area (the shading in the figure below has been added by the Applicant). *See*, column 3, lines 53-56.



Consequently, Venbrux does not teach or suggest a stent as claimed in independent claims 1, 108, or 109 and Applicant traverses and requests withdrawal of the rejection.

Dependent claims 91, 95, 100, 101, 110, 114, and 119-120, depend from claims 1 and 109, respectively. These claims are therefore patentable for at least the reasons discussed with respect to claims 1 and 109. Therefore, Applicant requests withdrawal of the rejection.

Rejections over Kranz

Claims 1, 91, 92, 94, 98-101, and 108 were rejected over Kranz. Kranz discloses a "biocompatible stent with radiopaque markers." Title of Kranz. Kranz further discloses that "[i]t is also possible to provide a coating for a regularly deformable, X-ray transparent stent segment, which reflects the X-rays." Column 2, lines 21-23. "Gold, silver or tantalum in particular are provided as material for the X-ray opaque element . . . ." Column 2, lines 31-32.

For reasons similar to those discussed above with respect to Richter, the gold, silver, and tantalum X-ray opaque materials of Kranz are not "drugs". Moreover, they are certainly not "polymers," as claimed (see, for example, claim 108), and a person having ordinary skill in the art would not consider them as such.

In light of the foregoing, Kranz does not disclose each and every claimed element of independent claims 1 and 108, respectively. And, pursuant to MPEP § 2131 "[a] claim is

anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (Quoting *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Consequently, Applicant traverses and requests withdrawal of the rejection of independent claims 1 and 108 and dependent claims 91, 92, 94, and 98-101.

Rejections over Scott

Claims 1, 91, 92, 94, 96-100, 108-11, 113, and 115-119 were rejected over Scott. This rejection is *traversed*.

With respect to independent claim 1, Scott does not disclose a stent having "a first biocompatible coating adhered directly on at least the metal outer surface . . . ," as is claimed. Similarly, Scott does not disclose a "stent having . . . [a] polymer contacting the outer metal surface . . . ," or a "stent comprising . . . a polymer or a drug coating adhered directly on at least the metal outer surface . . ." as claimed in claims 108 and 109, respectively.

As shown below in FIG. 3, Scott discloses a "sheath for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen . . . ." Abstract of Scott.

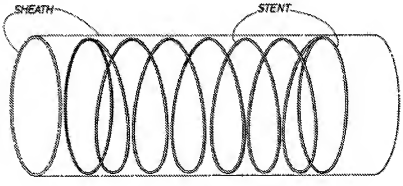


FIG 3

The Office Action's rejection ascribes an interpretation of the claim that is inconsistent with Applicant's Specification. Scott's "sheath" is not analogous to Applicant's claimed coating. For example, in paragraphs [0029] and [0067] and FIG. 11 Applicant discloses "another embodiment of the invention utilizing a sleeve." Paragraph [0029]. Applicant's embodiment comprising a sleeve is distinguished from Applicant's claimed invention comprising a

"coating."

In addition, Scott appears to distinguish between "coatings" and "sleeves." For example, at column 3, line 49 through column 4, line 14, Scott discusses the "inadequacies associated with polymer coatings directly applied onto the stent wires," and, as a solution, proposes "a separate sleeve to encompass the stent and serve as a local delivery device to prevent thrombosis." Column 4, lines 8-14.

Consequently, the Office Action's assertion that Scott discloses a coating as claimed is erroneous. Both Applicant's disclosure and the disclosure of Scott recognize that a coating is not a sleeve. The Office Action's interpretation of Applicant's claimed "coating" is inconsistent with the plain meaning of the word and Applicant's Specification. Therefore, Applicant requests withdrawal of the rejection of independent claims 1, 108, and 109.

With respect to dependent claims 91, 92, 94, 96-100, 110, 111, 113, and 115-119, these claims depend either directly or indirectly from claims 1 and 109, respectively. These claims are therefore patentable for at least the reasons discussed with respect to claims 1 and 109 and Applicant requests withdrawal of the rejection thereof.

Claim Rejections – Section 103

Claims 1, 91-101, and 105-123 were rejected over Berg in view of Scott, Nolting, and Jang. This rejection is *traversed*.

In making the aforementioned rejection, the Office Action asserts that "Scott discloses stainless steel . . . stents comprising a coating of a polymer and drug . . . ." Page 5. As discussed above, Scott discloses a sleeve, not a coating as is claimed.

Moreover, Scott teaches away from using a "coating" disclosing that the sleeve therein disclosed overcomes inadequacies of "coating". See, e.g., column 4, lines 8-14. Under the proper legal standard, a reference will teach away when it suggests that the developments flowing from its disclosures are unlikely to produce the objective of the applicant's invention. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

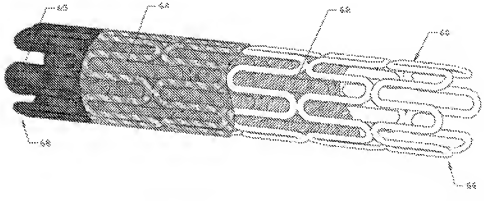
Consequently, a person having ordinary skill in the art would not be motivated to modify the stent of Berg with Scott, as the Office Action suggests. Instead, in light of the teaching of Scott, a person having ordinary skill in the art would be expected to ignore the

coating of Berg in lieu of the allegedly preferred sleeve of Scott.

With regard to the Nolting reference, as discussed in Applicant's previous response dated July 14, 2009, which is herein incorporated by reference, Nolting does not teach or suggest a "first biocompatible coating adhered directly on at least the metal outer surface of the first end portion of the main body portion, wherein the first biocompatible coating comprises a polymer or a drug contacting the metal outer surface, and wherein the metal outer surface and the metal inner surface of the middle portion are free of the polymer or drug" as is claimed in claim 1, a "polymer contacting the outer metal surface, wherein the polymer does not extend onto the outer metal surface of the middle portion of the stent" as is claimed in claim 108, or a "polymer or a drug coating adhered directly on at least the metal outer surface of the first end portion of the main body portion, wherein the metal outer surface and the metal inner surface of the middle portion are free of any coating comprising a polymer or a drug," as is claimed in claim 109.

Furthermore, a person having ordinary skill in the art would not modify the stent of Berg in light of Nolting in a way that would satisfy the recited claim language. As discussed previously and shown below in figure 8, Nolting discloses a "stent (60), a first thin membrane (62) defining a luminal surface, a second thin membrane (64) defining a vascular surface and a coating (65)." Column 10, lines 1-4.

FIGURE 8



Modifying the stent of Berg with the disclosure of Nolting would not produce a stent wherein the metal outer surface and the metal inner surface of the middle portion are free of any coating comprising a polymer or a drug. Indeed, neither Nolting nor Berg discloses this claimed subject matter. *See, e.g.*, Office Action at page 5 ("Berg is silent as to providing the

coating on an end portion and not on a middle portion of the stent.").

Modifying Berg with the disclosure of Nolting would be expected to produce a stent largely in accordance with the disclosure of Nolting. Specifically, the thin membrane (64) of Nolting extends the entire length of the stent. The coating 65 appears to be disposed over the thin membrane 64. Thus, it is not disposed "directly on" the stent, as is claimed. The coating of Berg is similarly disposed over the entire length of the stent. Therefore, in modifying the stent of Berg with that of Nolting, a person having ordinary skill in the art would be expected to add the coating {65) of Nolting to the proximal and distal end regions of the stent of Berg. *See* Nolting at column 10, lines 5-9. The resulting stent would have a thin membrane or polymer that extends the entire length of the stent. Such a device does not satisfy the claimed language, "wherein the metal outer surface and the metal inner surface of the middle portion are free of the polymer or drug," for example of claim 1, just as the stent of Nolting does not satisfy the claimed language (as discussed in Applicant's response dated July 14, 2009).

Consequently, the suggested modification still would not produce what is claimed in Applicant's independent claims. Therefore, Applicant requests withdrawal of the rejections thereof.

With regard to Jang, the alleged disclosure therein does not remedy the deficiencies discussed above with respect to independent claims 1, 108, and 109.

With regard to dependent claims 1, 91-101, and 105-107 and 110-123, these claims depend from claims 1 and 109, respectively. These dependent claims are therefore patentable for at least the reasons discussed with respect to claims 1 and 109. Consequently, Applicant requests withdrawal of the rejections.

Conclusion

Based on at least the foregoing remarks, Applicant requests withdrawal of the rejections and allowance of claims 1, 91-101, and 105-123. Favorable consideration and prompt allowance of these claims is earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,

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